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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,510	12/08/2006	Yitzhak Tor	15670-0198US1/SD2002-135	4141
20/985                      7590                      03/11/2011 FISH & RICHARDSON P.C. (SD) P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022				
			EXAMINER PESELEV, ELLI	
			ART UNIT 1623	PAPER NUMBER
			NOTIFICATION DATE 03/11/2011	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

# Office Action Summary

## Application No.

10/571,510

## Applicant(s)

TOR ET AL.

## Examiner

Ellie Peselev

## Art Unit

1623

**Period for Reply**  
-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 9-11, 13-17, 20-23, 25-28, 30-33, 37, 43, 44, 46-48 and 50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 9, 14-17, 20-23, 25-26, 31-33, 37, 43, 44, 46-48 and 50 is/are rejected.
- 7) ☒ Claim(s) 10, 11, 13, 27, 28 and 30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-592)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 22, 2010 has been entered.

Claims 1, 9, 14-17, 20-23, 25, 26, 31-33, 37, 43, 44, 46-48 and 50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for BODIPY conjugated to guanidinoaminoglycoside, does not reasonably provide enablement for any therapeutic agent conjugated to guanidinoaminoglycoside. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

A conclusion of lack of scope of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims.

The claims encompasses conjugation of any therapeutically agent to guanidinoaminoglycoside.

(B) The amount of direction provided by the inventor.

The working examples limited to the conjugation of a single therapeutic agent to guanidinoaminoglycoside, is clearly not commensurate with the full scope of the claimed invention.

(C) The existence of working examples.

The examples are limited to conjugation of BODIPY to guanidinoaminoglycoside.

(D) The level of predictability in the art.

A person having ordinary skill in the art at the time the invention was made, would not have been able to predict which specific therapeutic agent will exhibit an enhanced cellular uptake when conjugated to guanidinoaminoglycoside because molecules of different structural formula and sizes would not have been expected to produce similar results. For example, a conjugated protein and a conjugated metal would not have been expected to produce predictable results.

(E) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Because it cannot be predicted a priori which specific therapeutic agent will exhibit an enhanced cellular uptake when conjugated to guanidinoaminoglycosides, it would take an enormous amount of trial and error to test cellular uptake of therapeutically active agents having various structural formulas and including small molecules and large molecules.

Claims 10, 11, 13, 27, 28 and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's arguments filed July 22, 2010 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev  
/Elli Peselev/  
Primary Examiner, Art Unit 1623